IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE ANECDOTAL ADVERSE EVENT REPORTS

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Defendants" or "Pfizer"), respectfully submit this memorandum in support of their motion *in limine* to exclude anecdotal adverse event reports.

SUMMARY OF ARGUMENT

The Food and Drug Administration ("FDA") regulations define an "adverse drug experience" as an event "associated with the use of a drug in humans, ***whether or not considered drug related***." 21 C.F.R. § 314.80(a) (2010) (emphasis added). Pursuant to federal regulations, pharmaceutical companies are required to relay to the FDA any adverse drug experiences that are reported to the company. *Id.* § 314.80(c). Individuals who report adverse events are under no obligation to report accurately or completely. Moreover, the fact that an individual experienced an adverse event while taking a pharmaceutical product does not suggest that the event was caused by the product. *See id.* § 314.80(k). Indeed, any consumer complaint or inquiry suggesting an adverse drug reaction results in the creation of an adverse event report, no matter how frivolous or improbable. For these reasons, adverse event reports provide *no* valid scientific evidence that a particular medication causes any effect or "notice" of any such causal

relationship. Because such reports are unreliable hearsay, irrelevant to any issue in the case, and certainly more prejudicial than probative, this category of evidence should be excluded at trial.

ARGUMENT

I. ANECDOTAL ADVERSE EVENT REPORTS CONSTITUTE INADMISSIBLE HEARSAY

Under Federal Rules of Evidence 801 and 802, adverse event reports are classic examples of hearsay and double-hearsay, and are not subject to any of the hearsay exceptions enumerated in Rule 803. Adverse event reports are unsworn, out-of-court statements by clinical researchers, private physicians, individual patients or laypersons, lawyers, or other actors relating the purported experiences of patients prescribed Neurontin or other medications. In many instances, the "facts" set forth in the reports are second-hand (e.g., patient statements made to reporter-lawyer) or even third-hand (e.g., patient statements made to lawyer and related to reporter-paralegal), and thus constitute double- and triple-hearsay. If the reports are admitted, Defendants will have no opportunity to cross-examine the individuals who made the statements in these reports to determine their reliability, accuracy, or motivation. By the same token, Plaintiff cannot vouch for the accuracy of observations contained in the reports or for the motivations of the reporter.

As out-of-court statements offered to show that the patient prescribed Neurontin or other drugs experienced what they assert they experienced, adverse event reports are hearsay and should be excluded. *See Cameron v. Otto Bock Orthopedic Indus., Inc.*, 43 F.3d 14, 16 (1st Cir. 1994) (affirming trial court's exclusion of "product failure reports" sent from prosthetists to prosthetic leg manufacturer and holding that product failure reports did not satisfy business records exception); *DeLuca v. Merrell Dow Pharms, Inc.*, 791 F. Supp. 1042, 1050 (D.N.J. 1992) (adverse event reports "have inherent biases as they are second-or-third hand reports, are affected by medical or mass media attention, and are subject to other distortions."), *aff'd*, 6 F.3d 778 (3d Cir. 1993); *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 801 n.5 (D.D.C. 1986) (finding that adverse event report constituted inadmissible hearsay), *aff'd*, 857 F.2d 823 (D.C.

Cir. 1988); *Cosgrove v. Merrell Dow Pharms., Inc.*, 788 P.2d 1293, 1298 (Idaho 1989) ("The observations and information contained in adverse event reports are clearly hearsay . . . ."); *Muilenberg v. Upjohn Co.*, 320 N.W.2d 358, 363-64 (Mich. Ct. App. 1982) (holding that compilation of adverse event reports was hearsay).

II. ADVERSE EVENT REPORTS ARE INADMISSIBLE BECAUSE THEY ARE IRRELEVANT TO ANY ISSUE IN THIS CASE

A. Adverse Event Reports Should Not Be Admitted To Prove Causation

Adverse event reports are not probative of causation and, therefore, should also be excluded as irrelevant. While the MDL court has ruled that Plaintiff's experts' testimony on general causation is admissible under *Daubert*, *In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 158-59 (D. Mass 2009), these adverse event reports, standing alone, may not be introduced to prove causation. The plain language of Rule 703 states:

> Facts or data that are otherwise inadmissible shall not be disclosed to the jury by the proponent of the opinion or inference unless the court determines that their probative value in assisting the jury to evaluate the expert's opinion substantially outweighs their prejudicial effect.

Fed. R. Evid. 703. In this case, the probative value of adverse event reports as evidence of causation does not outweigh the prejudicial effect of allowing them into evidence.

The FDA has specifically acknowledged the untrustworthiness of adverse event reports with respect to the truth of their contents and their lack of probative value on the issue of causation. Likewise, the FDA has repeatedly cautioned that adverse event reports are not reliable evidence of causation. *See* 21 C.F.R. § 314.80(k) (2010) (cautioning that an inference of causation cannot be drawn from adverse event reports); *see also* Office of Biostatistics & Epidemiology, FDA, *Annual Adverse Drug Experience Report: 1996* (Oct. 30, 1997) (cautioning that an inference of causation cannot be drawn from the number of adverse event reports); Ctr. For Drug Evaluation & Research, FDA, *The Clinical Impact of Adverse Event Reporting* 5 (Oct. 1996), *available at* http://www.fda.gov/downloads/Safety/MedWatch/UCM168505.pdf (adverse event reports may be not used to calculate drug risks); Letter from Gerald Faich, Pharmaceutical

Safety Assessments, Inc., to Public Record (Apr. 8, 2003), *available at* http://www.fda.gov/ohrms/dockets/dailys/03/apr03/041803/02N-0528_emc-000008-01.doc ("Routine causality assessments of spontaneous reports were dropped at FDA in 1983 because of its limited value and because it was a major source of delay in entry and contributed to backlogging. Hopefully, regression to an inefficient and low utility activity can be avoided based on prior experience.").

Furthermore, with respect to this litigation in particular, the FDA has cautioned that adverse event reports are unhelpful in determining whether Neurontin causes suicide. In an email to Dr. Alexander Ruggieri, the FDA stated:

> Concerning your question why data from the FDA Adverse Event Reporting System (AERS) has not been analyzed or made public, the agency does not believe that spontaneous post-marketing reports can be interpreted appropriately in this situation. Patients taking these drugs have a high background rate of suicidal thoughts/behaviors, and it is not possible to tell from AERS reports, whether the drug caused them. In the agency's view, the only way to establish whether or not the drugs are responsible for suicidality is to analyze controlled trial data.

(Ex. A, E-mail from Donald Dobbs, FDA Consumer Safety Officer, to Dr. Ruggieri on Apr. 1, 2008; *see also* Ex. B, Letter from Russell Katz, M.D., Food and Drug Administration, to Andrew G. Finkelstein on Apr. 12, 2005 (responding to Plaintiff's counsel's letter providing "MedWatch forms of patients whom [Mr. Finkelstein] state[d] committed suicide while being treated with Neurontin" and emphasizing that, "in the absence of an appropriate control group, it will be difficult, if not impossible, to assess the role of any other factors that might explain these events, such as concomitant medications").) Thus, even in this particular scientific context and despite taking other regulatory actions, the FDA has reaffirmed its longstanding position that adverse event reports are not probative on the issue of causation.

In accordance with the FDA's clear position, numerous courts have excluded adverse event reports as scientifically unreliable. As one district court succinctly observed, case reports are "universally recognized as insufficient and unreliable evidence of causation." *In re Diet*

Drugs Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586, at *15 (E.D. Pa. Feb. 1, 2001) (collecting cases); *see also Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1411 (D. Or. 1996) ("[C]ase reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls.").[1]

In this case, the MDL court likewise recognized the dubious scientific value of adverse event reports. "To be sure, Plaintiffs and Defendants agree that adverse event reports ('AERs') – whether published in safety databases or the medical literature – have significant limitations." *In re Neurontin*, 612 F. Supp. 2d at 153; *see also In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1039-40 (D. Minn. 2007); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1253-54 (11th Cir. 2005). This is a fact confirmed by Plaintiff's own witnesses and experts who, in a previous trial, testified about the limited value of adverse event reports, as compared to controlled clinical data. (*See* Ex. C, Testimony of David Franklin, *Shearer v. Pfizer* 3/31/10 Trial Tran. at 129:12-22 ("Q. And if you're trying to prove something the more reliable evidence is the controlled study, not

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[1] *See also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, at 1250 (11th Cir. 2005) (noting that adverse event reports are "[u]ncontrolled anecdotal information offer[ing] one of the least reliable sources to justify opinions about both general and individual causation"); *In re Accutane Prods. Liab.*, No. MDL 1626, 2007 WL 1288354, at *3 (M.D. Fla. May 2, 2007) (noting that adverse event reports "reflect[] nothing more than an assessment of a possible relationship, not an actual relationship"); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 808 (N.D. Ohio 2004) (adverse event reports held "irrelevant to establish a material issue of fact"), *aff'd*, 447 F.3d 861 (6th Cir. 2006); *Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 682 (M.D.N.C. 2003) ("[Adverse event reports] are not scientific proof of causation."); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1050 (S.D. Ill. 2001) (noting that experts' case reports "make little attempt to isolate or exclude possible alternative causes, lack adequate controls, and lack any real analysis"); *Nelson v. Am. Home Prods. Corp.*, 92 F. Supp. 2d 954, 969, (W.D. Mo. 2000) ("[Adverse event reports] do not demonstrate a causal link sufficient for admission to a finder of fact in court."); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) ("Neither case reports nor adverse drug reaction reports contain scientific analysis with the safeguards of a controlled experiment. . . . Unlike epidemiological studies, they do not contain a testable and systematic inquiry into the mechanism of causation."); *Saari v. Merck & Co.*, 961 F. Supp. 387, 394 (N.D.N.Y. 1997) (noting that adverse event reports "neither confirm[] nor deny[] that there is any relationship" between alleged symptoms and a product); *Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996) ("[A]ccording to the FDA, . . . [such reports provide] no certainty that the suspect drug caused the reaction."), *aff'd*, 158 F.3d 588 (11th Cir. 1998); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("[C]ase reports are not reliable scientific evidence of causation, because they simply describe[] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.").

the anecdotal report? A. I would argue that the anecdotal report is not evidence. Q. Now, I don't want to belabor this – A. It's the lowest form of evidence. Q. The anecdotal report? A. Yes. Q. And that's because there might be other explanations for what you are observing? A. Exactly."); Ex. D, Testimony of Charles King, *Shearer v. Pfizer* 4/1/10 Trial Tran. at 127:13-129:1.)

Other courts have also voiced concerns about adverse event reporting spurred by litigants. *See Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999); *Hagaman v. Merrell Dow Pharms., Inc.*, No. 84-2202-S, 1987 WL 342949, at *8 (D. Kan. June 26, 1987). In examining Plaintiff's expert Dr. Blume at the general causation hearing, the MDL Court observed how spikes in adverse event reporting were aberrations adding little support to Plaintiff's scientific claims. (Ex. E, *Daubert* Hr'g Tr. at 160:2-162:11, 164:21-165:17, June 20, 2008 ("Judge Saris: Well, sure, but just as we just were doing going through that graph, it could be a difference in publicity, it could be a difference in reporting techniques. The Witness: Exactly, I agree. Judge Saris: I mean, the jumps look horrific when you first look at them, but then there are explanations, right?").) That concern is particularly acute in this case – by submitting 258 direct reports into the adverse event report database in a single day, Plaintiff's counsel has prevented further reliable use of that database. (*See* Ex. F, Letter from Andrew Finkelstein to FDA on Mar. 21, 2005.)[2] In fact, this reporting bias is something recognized by Dr. Blume as well as Plaintiff's counsel. (*See* Ex. G, April 4, 2008, Decl. of Keith Altman at ¶ 24 ("With respect to any notoriety bias, Dr. Blume has always requested that I confine analyses to data before the 3rd quarter of 2003 for signal detection purposes. She clearly recognized that such a bias was possible after that point in time and wanted to be sure that her opinions were not

[2] Consider, for example, that Plaintiff might offer adverse event reports based on cases such as Strickland, Mendoza, Fenelen, Ellis, and Wendorf in the MDL. Each of these cases was voluntarily discontinued and/or withdrawn from representation by Plaintiff's counsel after Plaintiff's counsel was required to certify that pursuit of the action was warranted. (*See* Mem. & Order [949], Nov. 9, 2007; Mem. & Order [890], Sept. 28, 2007.)

influenced by such data. On occasion, she would ask me to go beyond that point in time for the purpose of seeing the effect of the notoriety bias.")).

In sum, the reports at issue in this litigation are in no way immune to the pervasive scientific and evidentiary concerns that have earned adverse event reports universal disregard in proving causation. Thus, even if not offered for their truth, adverse event reports are unreliable on the issue of causation and should not be disclosed to the jury.

B. Anecdotal Adverse Event Reports Are Not Relevant To The Issue Of Notice

To the extent Plaintiff argues that she does not offer adverse event reports for their truth, but rather as evidence that Defendants had notice that Neurontin can cause suicide, such evidence is still inadmissible. Defendants do not dispute the existence of a certain number of adverse event reports.[3] But in order to prove that any of these reports put Defendants on "notice," the adverse event report would have to be "substantially similar" to the very unique facts and circumstances of this case. It is undisputed that Richard Smith had a unique medical history. It is impossible for Plaintiff to replicate these circumstances and/or prove substantial similarity based on the unreliable, unsubstantiated information contained in adverse event reports, some of which contain little substantive detail about any particular event.

The law of this Circuit disfavors evidence of other accidents or incidents, whether to prove notice or a product's propensity for harm, on grounds of relevancy and prejudice. *See Rye v. Black & Decker Mfg. Co.*, 889 F.2d 100, 102-03 (6th Cir. 1989) (substantial similarity required); *Engebretsen v. Fairchild Aircraft Corp.*, 21 F.3d 721, 732-33 (6th Cir. 1994) (substantial similarity required); *Pride v. Bic Corp.*, 54 F. Supp. 2d 757, 760 (E.D. Tenn. 1998) (substantial similarity required); *see also Duran v. Hyundai Motor Am., Inc.*, 271 S.W.3d 178, 198 (Tenn. Ct. App. 2008) ("[I]f the evidence of prior accidents is being offered to prove the existence of a particular hazard or danger, the party seeking to introduce the evidence must lay a

[3] In fact, the Neurontin labeling contained the words "suicidal" and "suicide gesture" in the adverse events section at the time Mr. Smith was prescribed Neurontin.

foundation establishing substantial similarity between the present accident and the prior accident.") (citing *John Gerber Co. v. Smith*, 150 Tenn. 255, 263 S.W. 974, 977 (1924)).[4]

In cases such as this one, courts have specifically excluded adverse event reports based on the absence of substantial similarity. *See Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 550-51 (W.D. Pa. 2003); *Wolf v. Proctor & Gamble Co.*, 555 F. Supp. 613, 622 (D.N.J. 1982). For example, in *Wolf*, the plaintiff argued that consumer complaints about various reactions would be admissible to prove that a tampon manufacturer had notice that its tampon could cause toxic shock syndrome. *See Wolf*, 555 F. Supp. at 621. The court rejected this argument because "complaints of a few women, out of what must have been thousands of [tampon] users, that they suffered these symptoms coincidental with their use of [the defendant's product], are not very probative of the fact that the defendants were put on notice of the defect at issue in this case." *Id.* at 622.

In this same manner, the adverse event reports proffered in this case are inadmissible as notice to Defendants of other accidents or incidents. The type and nature of the adverse events reported, the patients' pre-existing risk factors for suicide, the onset of symptoms, ingestion and dose of Neurontin, treatment compliance, concomitant medications, and the potential alternative causes for the adverse events are anything but "substantially similar." *See In re Neurontin Mktg., Sales Practices & Prods. Liab. Litig.*, 257 F.R.D. 315, 322-33 (D. Mass 2009) (denying class certification in Neurontin sales and marketing cases on similar grounds); *see also In re Paxil Litig.*, 218 F.R.D. 242, 249-50 (C.D. Cal. 2003) (denying class certification in antidepressant-suicide cases on similar grounds).

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[4] *See also Cameron*, 43 F.3d at 16 (substantial similarity required); *Vincent v. Louis Marx & Co.*, 874 F.2d 36, 43 (1st Cir. 1989) (substantial similarity required), *abrogated in part on other grounds by Knowlton v. Deseret Med., Inc.*, 930 F.2d 116 (1st Cir. 1991); *MacKinnon v. Skil Corp.*, 638 F.2d 270, 277 (1st Cir. 1981) (same); *Trull v. Volkswagen of Am., Inc.*, 187 F.3d 88, 98 n.9 (1st Cir. 1999) (affirming that the substantial similarity standard is appropriate in cases that "involve attempts by plaintiffs to bring evidence of other accidents before the jury to demonstrate dangerousness or notice of danger, a particularly prejudicial form of evidence when used to counter a defendant's assertion that its product is safe. At bottom, the 'substantially similar' requirement is a more particularized approach to the requirement that evidence be probative.").

In addition, because purported reports received by Defendants after Decedent's death have no conceivable bearing on the issue of notice, any adverse event report dated after May 13, 2004 (the date of Richard Smith's death) are irrelevant and inadmissible for that reason as well.

C. Anecdotal Adverse Event Reports Are Inadmissible Under Rule 403

Even if adverse event reports were relevant to the issue of causation or notice, Rule 403 provides an additional basis for excluding them on grounds that their probative value is outweighed by the danger of prejudice, confusion, misleading the jury, and undue delay. *See Duran*, 271 S.W.3d at 198 ("[E]vidence concerning prior accidents that does not satisfy the substantial similarity requirement is inadmissible" under Rule 403); *see also Cameron*, 43 F.3d at 17 ("[T]he lack of proof of similarity of circumstances reinforces any decision to exclude under Rule 403."); *Reynolds v. Warthan*, 896 S.W.2d 823, 828 (Tex. Ct. App. 1995) (holding trial court did not abuse its discretion in excluding incident reports dealing with Kwell, a topical lotion: "[T]he court properly excluded the reports since their marginal relevance was outweighed by the danger of confusing and misleading the jury.").[5]

In this case as well, there is a high likelihood that the jury would be confused and misled by the reports, which fail to take background rates, potential alternative causes and confounding factors, and the absence of a controlled comparison into account. *See, e.g.*, *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1046, 1050 (S.D. Ill. 2001); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). Moreover, disclosing these adverse event reports to the jury would necessitate undue delay in the form of mini-trials into the credibility of the declarants and the facts and circumstances surrounding the report. *See Uitts v. Gen. Motors Corp.*, 411

[5] There are also due process concerns associated with the introduction of adverse events reports. The United States Supreme Court has held that the Due Process Clause bars punitive damages from being awarded based on evidence or argument about alleged harm to non-parties. *See Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007) ("[T]he Constitution's Due Process Clause forbids a State to use a punitive damages award to punish a defendant for injury that it inflicts upon nonparties . . . *i.e.*, injury that it inflicts upon those who are, essentially, strangers to the litigation."). Consistent with these limitations, "a jury may not . . . use a punitive damages verdict to punish a defendant directly on account of harms it is alleged to have visited on nonparties." *Id.* at 355.

F. Supp. 1380, 1383 (E.D. Pa. 1974) (excluding reports of other accidents on grounds that mini-trials would be necessary to minimize prejudice to defendants, would lengthen trial, and divert attention from plaintiff's claim), *aff'd*, 513 F.2d 626 (3d Cir. 1975); *see also Cowgill v. Raymark Indus., Inc.*, 832 F.2d 798, 805 (3d Cir. 1987) (same).

This danger can be illustrated by examination of just one such Neurontin adverse event report. In Suspect Adverse Reaction Report No. 200551608, for example, a consumer reported that he had attempted suicide on two separate occasions while using Neurontin. However, follow-up with the patient's doctor revealed that the patient, a drug addict, did not attempt suicide at all, but accidentally overdosed on his drugs of choice – heroin, cocaine, cannabis and Valium – not once, but twice.

The danger of undue delay is especially prejudicial to Defendants. It will take little time for Plaintiff to introduce groups of adverse event reports into evidence. In contrast, it will take a substantial amount of time for Defendants to inquire into the unique facts and circumstances of each report in order to dispute the validity of Plaintiff's theories as to why the reports prove causation or notice.

CONCLUSION

As demonstrated above, adverse event reports are inadmissible hearsay. To the extent Plaintiff argues that she offers the reports not for their truth, but to prove causation and/or notice, they remain inadmissible. As to the causation argument, the FDA and courts alike (along with Plaintiff's own witnesses) recognize that adverse event reports are not proof of causation. As to the notice argument, there is no proof that any adverse event is substantially similar to the unique facts and circumstances of this case. Moreover, any adverse event report dated after Mr. Smith's death in May 2004 is completely irrelevant to the issue of notice. Finally, even if adverse event reports were relevant to issues of causation or notice, they should be excluded because of the danger of prejudice, confusion, and misleading the jury (the jury will give the reports undue weight) and undue delay (Defendants will be forced to inquire as to the facts and circumstances of each adverse event report in order to give it context).

For all of the foregoing reasons, adverse event reports should be excluded from evidence in this case.

Dated: April 16, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 16th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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